



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION II
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NEW YORK, NEW YORK 10007-1866

January 7, 2016

BY ELECTRONIC MAIL

Robert Law, Ph.D.
CPG Project Coordinator
de maximis, inc.
186 Center Street, Suite 290
Clinton, New Jersey 08809

Re: Lower Passaic River Study Area (LPRSA) Revised Draft 17 -Mile draft Baseline Human Health Risk Assessment – Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study (Agreement) CERCLA Docket No. 02-2007-2009

Dear Dr. Law:

The U.S. Environmental Protection Agency (EPA) is in receipt of the Cooperating Parties Group's (CPG) December 18, 2015 transmittal letter whereby the revised draft 17-Mile Baseline Human Health Risk Assessment (BHHRA) was submitted in accordance with Section X, Paragraph 46 of the Agreement. EPA will review the CPG's December 18, 2015 submission of the revised draft BHHRA and will respond in accordance with Section X, Paragraph 45 of the Agreement.

Your December 18, 2015 transmittal letter states the draft BHHRA has been revised under protest to conform to EPA's direction. Your letter also states that the CPG has strong objection and disagreement with EPA's directives, which you erroneously suggest are "to inflate risk estimates." However, the letter acknowledges that EPA engaged in an extensive process with the CPG in which we worked through comments and questions on the draft BHHRA, in an effort to bring this document to completion, and we understand from your letter that the revised document does reflect EPA's directions and comments.

Most of the CPG's objections, as described in the December 18, 2015 letter, have been previously raised by the CPG and addressed by EPA:

"Conflating Current and Future Risk" – EPA and the CPG fully discussed this issue in the context of the dispute resolution referenced on the first page of your December 18, 2015 letter (Dispute Resolution Issue 1). EPA acknowledges that CPG does not agree with EPA's decisions in the dispute resolution.

“Non-Site-Specific and Unrealistic Assumptions” – The issues raised by the CPG under this topic were the subject of the dispute resolution referenced on the first page of your December 18, 2015 letter (Issue 5).

- Bullet 1. The CPG’s reference to the fish and crab consumption rates, as with its comment above, addresses an issue discussed and decided in the context of the Dispute Resolution. EPA acknowledges that the CPG does not agree with the decision. EPA notes that additional information regarding exposures to a family of four was introduced in this comment. Evaluation of risks to a family of four is inconsistent with EPA Superfund guidance that requires evaluation of risks to the Reasonably Maximally Exposed (RME) Individual. Further, the text in this bullet indicates that the EPA determined that the adult angler is exposed for a period of 24 years, whereas EPA has directed the CPG to update the revised draft BHHRA to incorporate the update Superfund Standard Default Exposure Factors, published in 2014, which includes the assumption of 20 years of exposure for the adult.
- Bullet 2. The CPG indicates EPA ignored two creel angler surveys conducted in the LPRSA. EPA’s concerns with the survey approach utilized by Tierra Solutions, Inc. were documented and discussed in detail with the CPG in the Dispute Resolution. In 2009, the CPG proposed its own creel angler survey, and EPA has explained our concerns with the uncertain results of such a survey. As EPA recently noted, the issue of suppression was raised by the CPG’s peer review panel and remains a concern. Nevertheless, EPA indicated that the CPG could make references to its creel angler survey anecdotally. Further, EPA agreed that both surveys could be discussed in the uncertainty section of the BHHRA.
- Bullet 3. The CPG indicates EPA did not consider potential cooking losses in preparation of fish and crabs. This issue was addressed and decided in the dispute resolution. The BHHRA considers cooking loss in the evaluation of risks to the Central Tendency Exposed (CTE) individual. In addition, EPA reviewed additional information submitted by the CPG regarding cooking loss and approved modification to the cooking loss percentage for PCBs, for the CTE individual.

“Misrepresents PCB Risks” – Consistent with EPA’s 1996 “PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures (EPA #EPA/600/P-96/001F – September 1996, Example #3 page 62) the approach provided in EPA’s comments indicates dioxin-like PCBs and non-dioxin-like PCBs are to be summed. EPA is not aware of updates to this guidance that would change this approach.

“Consciously-Biased Selection of the Largest Fish Specimens” – The CPG’s letter is somewhat ambiguous. If this concerns EPA’s direction that carp consumption be evaluated in the BHHRA, as previously discussed, humans consume carp and the other fish species that were evaluated in the BHHRA, whereas smaller fish species such as mummichog are consumed by

ecological receptors and not humans. Surveys of anglers have not identified mummichog as a species consumed by humans and, as such, this species was not included in the BHHRA. Comments regarding cooking loss were addressed above.

“Refusal to Acknowledge the Severe and Significant Pathogen Risk” – As discussed in your letter, pathogens are not CERCLA constituents. As such, they are not evaluated in CERCLA BHHRA. However, EPA has not, as implied in your letter, directed the CPG to remove all references to pathogens from the BHHRA.

“Underestimation of the Contribution of Background Conditions on Site Risk” – EPA’s directions with respect to evaluation of background are consistent with the 2002 EPA guidance titled “Role of Background in the CERCLA Cleanup Program” (OSWER 9285.6-07P). Consistent with this guidance, as EPA has advised in our comments, the evaluation of background concentrations can be included in the BHHRA Uncertainty Section. This guidance (see Appendix B) specifically indicates Chemicals of Potential Concern (COPCs) should not be removed from consideration based on background. The text specifically states: “...In light of more recent guidance for risk-based screening (EPA, 1996 and EPA, 2000) and risk characterization (EPA, 1995c), this policy recommends a baseline risk assessment approach that retains constituents that exceed risk-based screening characterization. This approach involves addressing site-specific background issues at the end of the risk assessment, in the risk characterization.” This guidance was the basis for the approach EPA provided to the CPG in completion of the BHHRA.

In summary, EPA does not agree that our instructions create “compounding conservatism” resulting in unrealistic risk estimates. Rather, consistent with the National Contingency Plan goals of protecting human health and the environment, EPA directed the CPG to use an appropriately health protective, but not unrealistic, combination of average and high end (>90th percentile) exposure assumptions for the RME individual. As we have previously noted, some risks and hazards could be underestimated, given lack of toxicity data for a number of chemicals, use of surrogate data, use of high end values that are not the highest percentile, and use of average exposure assumptions such as body weight and skin surface area. Further, even the CTE scenario demonstrates non-cancer hazards that exceed the goal protection of a Hazard Quotient = 1.

“2014 Site-Specific Human Health Risk Assessment (SSHRA)” – The CPG has enclosed a copy of this document, which the CPG prepared as part of its comments on the Proposed Plan for the lower 8.3 miles of the Lower Passaic River, and now asks that EPA consider the results of the SSHRA for the 17-mile remedial decision making process. Given that, as described by the CPG, EPA and the CPG have gone through an extensive review and discussion of comments on the draft BHHRA, in an effort to arrive at an approvable document that is consistent with CERCLA guidance and policies, this request is more than puzzling. The 17-mile BHHRA, once approved by EPA, is the document that will provide the human health risk evaluation necessary for developing remedial alternatives and guiding remedy selection.

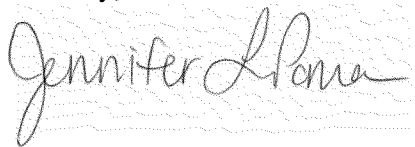
EPA will address comments on the RI/FFS and Proposed Plan for the lower 8.3 miles of the Lower Passaic River, including those submitted by the CPG, in the Responsiveness Summary issued with the Record of Decision (ROD) for the lower 8.3 miles.

“Revised 17-mile BHHRA Review” – EPA was not able to approve the CPG’s June 2014 submission of the draft BHHRA in whole or in part. EPA’s comments are so extensive and overarching that, as EPA has consistently advised, the revised document will be subject to a full review. EPA’s extensive comments reflect the fact that the draft BHHRA was not conducted in a manner that is consistent with EPA guidance and policy regarding CERCLA risk assessments. EPA’s review, and review by the partner agencies, will not be time wasted if the review confirms that the revised draft BHHRA appropriately incorporates EPA’s comments as discussed with the CPG in numerous call, emails and letters, such that EPA can approve it and the RI/FS process can proceed.

Finally, as the CPG is well-aware, and as reflected in any public discussion by EPA of the schedule for completion of the 17-mile RI/FS, the schedule is contingent upon and should be considered in context of whether the CPG takes the direction EPA has provided on submission of documents.

Please let me know if you have any questions.

Sincerely,

A handwritten signature in cursive script, reading "Jennifer LaPoma", written over a series of horizontal dotted lines.

Jennifer LaPoma, Remedial Project Manager
Lower Passaic River Study Area RI/FS